Qualitative study to determine how Chronic Kidney Disease is managed by healthcare professionals in primary care.

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Name & Role	**Date**	**Signature**

Study Management Group

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Statistician: N/A

Study Management:

Study Coordination Centre

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Clinical Queries

Clinical queries should be directed to Dr Rakesh Dattani who will direct the query to the appropriate person

Sponsor

Imperial College London is the main research Sponsor for this study. For further information regarding the sponsorship conditions, please contact the Head of Regulatory Compliance at:

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This protocol describes the "Qualitative study to determine how Chronic Kidney Disease is managed by healthcare professions in primary care" study and provides information about procedures for entering participants. Every care was taken in its drafting, but corrections or amendments may be necessary. These will be circulated to investigators in the study. Problems relating to this study should be referred, in the first instance, to the Chief Investigator.

This study will adhere to the principles outlined in the UK Policy Frame Work for Health and Social Care Research. It will be conducted in compliance with the protocol, the Data Protection Act and other regulatory requirements as appropriate.

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GLOSSARY OF ABBREVIATIONS

CKD	Chronic Kidney Disease
ESRD	End Stage Renal Disease
ICB	Integrated Care Board

KEYWORDS

Type 2 Diabetes Meliitus, Diabetic Kidney Disease, Chronic Kidney Disease

STUDY SUMMARY

TITLE Qualitative study to determine how Chronic Kidney Disease is managed by healthcare professions in primary care.

DESIGN Qualitative

AIMS To better understand how healthcare providers in primary care within the National Health System in the United Kingdom, manage Chronic Kidney Disease (CKD). Through this we hope to be able to identify ways in which we can improve the overall care of patients with CKD.

OUTCOME MEASURES The primary outcome measure is to determine current understanding on the management of CKD and to identify ways in which the screening, diagnosis, and management of patients at risk of CKD can be improved upon.

POPULATION Doctors, clinical pharmacists, and advanced nurse practitioners, working in primary care.

ELIGIBILITY Primary care doctors (General practitioners) and health care providers (clinical pharmacists, and advanced nurse practitioners working in primary care across the United Kingdom.

DURATION 6 months

1. INTRODUCTION

1.1. BACKGROUND

15% of the population in England aged >35 years of age have Chronic Kidney Disease (CKD). This results in 45,000 premature deaths, 100,000 excessive hospitalisations and £1.45 billion in costs to the NHS per year. Type 2 Diabetes is the commonest cause, with other common causes for CKD including but not limited to hypertension, ischaemic heart disease, heart failure and multisystemic disorders.

With the rising prevalence of diabetes, hypertension, and ischaemic heart disease amongst other clinical risk factors for CKD, the prevalence of CKD is expected to increase, with a substantial proportion of patients developing cardiovascular complications or progressing to ESRD. Primary care is instrumental in the screening of patients for CKD in the presence of known clinical risk factors as well as the early and effective management of confirmed CKD with prognostically beneficial medication. With prior working by myself highlighting the lack of screening of patients for CKD in the presence of clinical risk factors for CKD in North West London, alongside poor prescribing practices of prognostically beneficial medications. We therefore aim to better understand how healthcare professionals working in primary care could be better supported to screen patients for CKD and ensure appropriate subsequent management.

1.2. RATIONALE FOR CURRENT STUDY

Chronic Kidney Disease is a progressive condition that affects more than 10% of the general population worldwide, resulting in in excess of 800 million people currently affected. With the rising prevalence of Type 2 Diabetes, hypertension and ischaemic heart disease amongst other clinical risk factors for CKD, the prevalence of CKD over the coming ten years is expected to increase 2-3 fold. CKD is associated with significant degree of morbidity with patients not only going on to develop end stage renal disease, but also an array of cardiovascular diseases, resulting in premature morbidity and mortality resulting in an overall poor quality of life.

Primary care is vital in the 1. screening of patients with clinical risk factors for CKD 2. Diagnosis and coding of CKD and 3. Management of CKD. However, through prior work done by our group, we have identified poor screening of patients with clinical risk factors for CKD, poor coding of patients post diagnostic tests confirming CKD, poor communication with patients with regards to CKD diagnosis, cause and long term outcome in addition to inadequate prescribing of prognostically beneficial medication. This study therefore aims to determine how healthcare professionals in primary care screen for, diagnose and manage CKD in the community. Furthermore, it aims to determine areas done well as well as areas where improvement is needed to improve a patient's clinical journey and management. This will be done in the form of an online questionnaire and focus groups, advertised via Integrated Care Boards (ICB's) across the United Kingdom. Through this, we hope to gain further insight into areas of clinical management done well and areas of improvement as well as how primary care feel current management could be improved upon, obstacles faced, additional resources required and how they could be better supported by hospital specialists. Study results will be analysed and published in a peer reviewed journal with recommendations made with regards

to how care should be altered to help delay and prevent CKD onset and progression alongside the associated health care complications.

2. STUDY OBJECTIVES

The main research objective is to determine the current understanding amongst primary care health care professionals with regards to the screening and management of CKD, in addition to developing an understanding of the barriers faced by primary care in ensuring optimal clinical care. By gaining a better understanding of how GPs looking after patients with risk factors for CKD/confirmed CKD manage their patients, we hope to be able to identify areas of improvement, in order to create change and prevent the onset and progression of CKD.

3. STUDY DESIGN

The study is designed in the form of an online questionnaire, with participants recruited through advertisement of the study through ICB's across the United Kingdom. Qualiatrics.com will be utilised to create and share the questionnaire, with participants expected to take to 15 minutes to complete the questionnaire in total. The main research objective is to identify ways in which the management of patients with clinical risk factors for CKD can be improved upon in primary care. By gaining a better understanding of the barriers faced by healthcare professionals in primary care will allow us to identify new ways in which to improve patient care and management. Furthermore, we will seek to better understand ways in which healthcare professionals in primary care feel they could be better supported to prevent or delay progression of CKD and associated complications. Their views on the use of a risk prediction score and biomarkers for the diagnosis and assessment of progression will be sought as well as their opinions on the use of digital health within primary care for patients with CKD.

The study will be validated by primary and secondary care clinicians. Following validation and HRA approval, Integrated care boards (ICBs) across the UK will be sent an online link to the questionnaire and requested to share amongst health care providers within their ICB. The participant information sheet will be presented electronically, and participants consented electronically utilising Qualiatrics.com. Participants will be asked if they are willing to partake in an online focus group (lasting up to 1 hour in total) to further discuss the study and gain a further understanding of how care could be improved. For those willing to take part, an email address contact will be requested as a mode of communication between study organisers and participants. Participation is completely voluntary, and participants may change their decision at any time. Participants can withdraw consent at any time prior to the end of the focus group and can leave the session without any explanation. There is no financial incentive for clinicians partaking in the focus groups. Focus groups will be recorded utilising Microsoft Teams, with focus groups transcribed anonymously within 1 week of the focus group and the recording subsequently deleted. The

transcribed focus group will be deleted form records within 1 week, with the transcription stored electronically on the Imperial College Server.

Data from both components of the study will subsequently be analysed, with recommendations made of changes required to improve the screening and management of patients at risk of CKD.

4. PARTICIPANT ENTRY

4.1. PRE-REGISTRATION EVALUATIONS

No tests are required to be done prior to the patient entering the study.

4.2. INCLUSION CRITERIA

Doctors, clinical pharmacists, and advanced nurse practitioners, working in primary care.

4.3. EXCLUSION CRITERIA

Secondary care health care professionals.

4.4. WITHDRAWAL CRITERIA

Participants can withdraw at any point prior to submission of the online questionnaire. Questionnaires left prior to completion, will not be submitted and no data will therefore be retained. Once submitted, responses cannot be withdrawn as all data is collated collectively and anonymously. With regards to the focus group, participants can exist the online focus group at any time without explanation. Where participants withdraw, responses given by the individual will no longer be transcribed and considered. Once the focus group is transcribed and focus group recording deleted, it will not be possible to withdraw responses due to the anonymous nature in which the focus group will be transcribed prior to its deletion.

5. ADVERSE EVENTS

Not applicable.

6. ASSESSMENT AND FOLLOW-UP

Given the nature of the study, an online anonymous questionnaire/focus group there will be no follow up or assessment of study participants.

7. STATISTICS AND DATA ANALYSIS

This is a qualitative study, with qualitative methods applied to analyse the data generated. The qualitative data analysis approach will systematise descriptive data collected through the online questionnaire and subsequent focus groups, with the aim being to identify patterns and themes behind the interviews, surveys, and observations and interpreting it. The method aims to identify patterns and themes behind textual data. Specific analysis undertaken will utilise: 1. Discourse analysis whereby we will review the received answers from the questionnaire and the transcript form the focus groups to determine relationships between the received information and its context. 2. Conversion of qualitative data within the online questionnaire to quantitative data to allow for conclusions to be made 3. Thematic analysis for the transcript of the focus group to identify themes on how patients feel their care would have been improved upon.

Data and all appropriate documentation will be stored for a minimum of 10 years after the completion of the study, including the follow-up period.

8. REGULATORY ISSUES

8.1. ETHICS APPROVAL

The Study Coordination Centre has sought approval from the Health Research Authority (HRA), who deemed HRA approval not necessary. The study will be conducted in accordance with the recommendations for physicians involved in research on human subjects adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

8.2. CONSENT

Consent to enter the study must be sought from each participant only after a full explanation has been given, an information leaflet offered and time allowed for consideration. Participant consent will be obtained electronically utilising Qualiatrics.com. The right of the participant to refuse to participate without giving reasons must be respected. All participants are free to withdraw at any time from the protocol without giving reasons and without prejudicing further treatment.

8.3. CONFIDENTIALITY

The Chief Investigator will preserve the confidentiality of participants taking part in the study and is registered under the Data Protection Act.

Data will be pseudo anonymised.

8.4. INDEMNITY

Imperial College London holds negligent harm and non-negligent harm insurance policies which apply to this study.

8.5. SPONSOR

Imperial College London will act as the main Sponsor for this study.

8.6. FUNDING

There is no specific funding for this study. There are no investigator payments. Health care professionals undertaking the questionnaire and focus groups will not receive any payment for their participation.

8.7. AUDITS

The study may be subject to audit by Imperial College London under their remit as sponsor and other regulatory bodies to ensure adherence to GCP and the UK Policy Frame Work for Health and Social Care Research.

9. STUDY MANAGEMENT

The day-to-day management of the study will be co-ordinated through Imperial College London.

10. PUBLICATION POLICY

Study results will be analysed and published in a peer reviewed journal with recommendations made with regards to how care should be altered to improve the screening, coding and management of individuals with clinical risk factors for CKD/confirmed CKD.